TESTIMONY OF
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CENTER FOR MEDICAID AND STATE OPERATIONS
CENTERS FOR MEDICARE & MEDICAID SERVICES
ON
MEDICAID PRESCRIPTION DRUG REIMBURSEMENT
BEFORE THE
HOUSE ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGTAIONS

DECEMBER 7, 2004

Mr. Chairman, members of the subcommittee, thank you for your invitation to appear this morning to discuss Medicaid prescription drug reimbursement. Coverage of outpatient prescription drugs is an optional benefit for Medicaid programs. All states currently provide prescription drug coverage, which is critically important to Medicaid beneficiaries. However, this benefit is one of the greatest costs for the states. In fiscal year 2002, Medicaid drug expenditures were $29.3 billion out of $258.2 billion in total Medicaid spending or 11.3 percent. In addition, Medicaid drug spending increased at an annual average rate of 19 percent from fiscal years 2000 to 2002, while Medicaid spending as a whole grew 12 percent annually during that period. In 2003, Medicaid spent more than $34 billion on prescription drugs (See Chart 1). Of this amount, 23 percent was spent on drugs commonly prescribed to treat mental health conditions (See Chart 2). Furthermore, spending varies based on the specific medication prescribed. For example, under analgesics and anesthetics, the mean reimbursement for Celebrex is $112 per prescription, compared to $12 for ibuprofen (See Chart 3). In addition, the 29 most commonly prescribed drugs account for 25% of Medicaid spending on prescription drugs (Chart 4). Spending on prescription drugs claims varies by state. The average claim ranges from approximately $40 to more than $60 (See Chart 5). Therefore, it is important that both the Federal government and the states ensure that Medicaid programs pay for prescription drugs appropriately.

States Determine Payment to Providers

Medicaid operates as a provider payment program. States may pay health care providers directly on a fee-for-service basis, or states may pay for Medicaid services through various

prepayment arrangements, including payments to managed care plans. Within Federally imposed upper limits and specific restrictions, each State has broad discretion in determining the payment methodology and payment rate for prescription drugs, and what to pay pharmacists in dispensing fees. Generally, payment rates must be sufficient to enlist enough providers to ensure covered services are available at least to the extent that comparable care and services are available to the general population within a geographic area. Providers participating in Medicaid must accept Medicaid payment rates as payment in full. It also is important to note that prices have increased between 5 percent and 7 percent in recent years. An increase in utilization, as well as an increase in the Medicaid population has helped to increase the mean reimbursement per prescription (See Chart 6).

CMS Involvement with Medicaid Drug Pricing

While the States are largely responsible for managing their prescription drug benefit, Federal law authorizes CMS to ensure the Federal government receives a good price for prescription drugs. For example, the Medicaid Drug Rebate Program affords Medicaid programs the opportunity to pay for drugs at discounted prices, which are similar to those offered by pharmaceutical manufacturers to other large purchasers. In addition, Medicaid programs have a number of options to set prices for prescription drugs, including the Federal Upper Limit (FUL), maximum allowable cost (MAC), and wholesale acquisition cost (WAC) programs.

Medicaid Drug Rebate Program Controls Costs

Federal statute requires manufacturers to enter into an agreement with the Secretary of Health and Human Services, on behalf of the states, to provide rebates for covered outpatient prescription drug products paid for by Medicaid through the Medicaid Drug Rebate Program. Manufacturers that do not sign an agreement are not eligible for Federal Medicaid coverage of their product(s). Except for some statutory limitations, if a Medicaid program opts to cover prescription drugs for their beneficiaries, it must provide coverage and reimbursement for all covered outpatient drug products manufactured by companies that have entered into a rebate agreement with CMS, as Congress has guaranteed access to the Medicaid market for those drug manufacturers that provide rebates. Approximately 550 pharmaceutical companies participate in this program. Currently, 49 states and the District of Columbia participate in the Medicaid Drug

Rebate Program (Arizona has an 1115 waiver that exempts it from participating in the Medicaid Drug Rebate Program).

Manufacturers submit their Average Manufacturer Price (AMP) and Best Price (BP) to CMS. Using the AMP and BP, CMS calculates the rebate amount and informs the states. The rebate is calculated differently depending on the type of drug. For generic drugs, the rebate is 11 percent of AMP. For brand-name prescription drugs, the rebate is calculated in two ways. Basic rebates for brand-name drugs are the greater of 15.1 percent of the AMP or AMP minus BP. In addition, if the price of a drug increases at a rate faster than the consumer price index from a base year, the manufacturer would owe the state the difference dollar for dollar. States receive rebates from manufacturers based on states' quarterly data on the utilization of the manufacturers' drugs. The Drug Rebate Program was enacted out of concern for the costs the Medicaid program was paying for outpatient drugs. In FY 2003, manufacturers paid rebates to states of about $6.4 billion for covered outpatient drugs. The program gives Medicaid programs the opportunity to obtain discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.

States that wish to pursue Medicaid supplemental rebates in addition to rebates already received under the National Drug Rebate Agreement have the option to negotiate such rebates with drug manufacturers as specified in Federal law. In recent years, CMS has approved plan amendments that allow states to negotiate additional state-specific supplemental rebates for their Medicaid population or participate in a multi-state pooling supplemental rebate agreement. Rebates received under state supplemental agreements are shared with the Federal government at the same rate as the national rebates.

Currently, 33 states have Medicaid supplemental rebates, including those states in multi-state pooling arrangements. Twenty-six states have negotiated rebates on their own. For example, Florida began collecting state-only supplemental rebates in 2001 in conjunction with the establishment of its Preferred Drug List (PDL). Currently, the state receives supplemental rebates on brand name drugs, but not on generics. The state received rebates of $51 million in FY 2003 and does not expect to lose participation from any of the approximately 80 manufacturers that currently pay supplemental rebates.

Medicaid Federal Upper Limit Cuts Costs

One proven method to reduce drug costs for States and to ensure the government is a prudent purchaser of prescription medications is the use of generic medications instead of more expensive brand name pharmaceuticals. As you know, Mr. Chairman, generic drugs are typically significantly less expensive than their brand-name counterparts (See Chart 7). This is achieved through the use of the Federal Upper Limit (FUL), a program that caps Medicaid payments for brand name drugs that have therapeutically equivalent generic medications available. As a result, the FUL program, which achieves savings by taking advantage of current market prices, helps to significantly reduce pharmacy costs for both the states and the Federal government.

Through the FUL program, CMS sets an upper limit reimbursement amount for drugs that meet certain criteria. However, not all drugs are subject to the FUL pricing. To establish the FUL for a drug, CMS examines the FDA's Orange Book data to determine whether all the formulations of a drug product approved by the FDA are therapeutically equivalent. When all of the versions of that drug are not therapeutically equivalent, there must be at least three therapeutically equivalent drug products. Once a product has met the FDA criteria, CMS verifies that it meets the necessary compendium criteria by consulting the national drug-pricing compendium (Red Book, First Data Bank, and Medi-Span) to verify that there are at least three suppliers of the drug listed. If there are three suppliers, CMS sets the FUL at 150 percent of the lowest price (Average Wholesale Price, Wholesale Acquisition Cost, or Direct Price). A state's aggregate payment for all Medicaid prescription drugs with a FUL must not exceed, in the aggregate, the payment levels established by the FUL program. The aggregate cap allows states to increase or decrease the cost of individual prescription drugs in accordance with state or local markets while maintaining the overall savings created by the FUL program. States may exceed the FUL price for individual prescription drugs as long as their aggregate expenditures do not exceed the amounts that would have otherwise been spent by applying the FUL limit plus a reasonable dispensing fee.

CMS uses a 150 percent mark-up so that FUL prices are high enough to ensure that pharmacists can stock an equivalent product without a loss on acquisition costs. The mark-up also assures that FUL prices are low enough so that Medicaid will not pay too much for a prescription drug that is included on the list. The 150 percent mark-up is intended to balance the

interests of both pharmacists and the government in achieving efficiency, economy, and quality of care. In addition, to ensure the most accurate prescription drug pricing data, CMS has actively worked with the publishers of the compendium to resolve FUL pricing issues and to encourage the collection of accurate data. Because of the complexity and volatility of the drug marketplace, it is impossible to be certain that pricing or the inclusion of a drug on the FUL list is 100 percent accurate. CMS has an on-going process in place to ensure that any necessary revisions to the list can be identified and completed. As new information becomes available, CMS compiles a list of changes that is released periodically to the agency's regional offices. The regions provide the information to the states, which notify providers. CMS also posts the changes on its website at www.cms.hhs.gov/medicaid/drugs/drug10.asp.

We greatly appreciate the various reports of the Office of Inspector General on its review of prescription drug prices and the FUL program. While we value their work, in regards to the FUL program, it must be examined in its entirety. Specifically CMS must establish a drug product's eligibility for the FUL list that includes verification with the suppliers of the drugs that are necessary to assure availability.

Utilizing Maximum and Wholesale Costs

Maximum Allowable Cost (MAC) programs are designed to ensure Medicaid programs pay appropriate prices for generic and multi-source brand drugs. Typically, States administering the MAC programs will publish lists of selected multi-source and generic drugs with the maximum price at which Medicaid will reimburse for those medications. Pharmacies generally will not receive payments that are higher than the MAC price. These programs differ from the FUL list, as states have more discretion in determining what drugs to include on the MAC list. Instead of the MAC, some states use wholesale acquisition costs (WAC), which is the listed price supposedly paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug.

Additional Tools Are Available to States to Address High Prescription Drug Costs

In addition to the rebate program, and as a result of increasing prescription drug costs, State Medicaid programs have implemented a variety of cost-containment mechanisms in their drug programs over the past few years. These mechanisms have allowed States to reduce their pharmacy expenditures and maintain beneficiary access to a vital part of their overall health care. While some of the pharmacy techniques employed by the States represent prudent management of program costs, the Medicaid drug benefit remains a State option with benefits and limitations that vary from State to State. CMS can provide consultation and support to assist states in using these and other methods to lower their drug costs without compromising quality of care. However, aside from federal regulations, most Medicaid cost containment decisions ultimately are made at the state level. States use a variety of methods to pay for prescription drugs. In addition, they use a variety of cost control measures. For example, the use of copayments, generic substitution, and disease management programs are handled at the state level (See Chart 8).

Copayments Contribute to Cost Containment

At their discretion, states may impose nominal deductibles, coinsurance, or copayments on some Medicaid beneficiaries for certain services. Nominal copayments are a tool available to states as a cost containment measure. The use of copayments for prescription drugs varies from state to state. Nineteen states have no copayment, and the vast majority of the remaining states require a copayment ranging from 50 cents for generic drugs to $3.00 for brand-name prescriptions. Cost sharing limits are set by Federal regulation and have not changed in many years. In addition, some groups are totally exempt from cost-sharing by law. Pregnant women, children under age 18, and hospital or nursing home patients who are expected to contribute most of their income to institutional care are exempt from cost-sharing.

States' Aggressive Generic Substitution Saves Money

Generic drugs account for more than half of all prescriptions in the United States. Many private health plans have generic drug use rates of more than 90 percent, but generics are not as widely used in some Medicaid programs. The low prices of generic drugs in the United States are an important potential source of savings for states. The potential cost-savings by the use of

generic drugs has prompted 39 states to require that the generic version of a drug be dispensed to Medicaid beneficiaries when available. Under these mandatory generic substitution policies, the brand name drug remains available to beneficiaries through prior authorization. Examples of "best practices" involving generic drugs include Minnesota and Idaho. For example, Minnesota has had a mandatory generic substitution policy in place for nearly a decade. This saves the State $10 million annually. Idaho also has a mandatory generic substitution policy, which increased the percentage of generic drugs dispensed from 46.7 percent in fiscal year 2002 to 53 percent in fiscal year 2003. Idaho's policy saved $11.7 million in State and Federal funds.

Drug Utilization Review Protects Patients and Reduces Costs

Congress created the Medicaid Drug Utilization Review (DUR) Program through the Omnibus Budget Reconciliation Act of 1990. The program promotes patient safety by an increased review and awareness of outpatient prescribed drugs. Under the law, states are required to complete annual reports, which provide an excellent measurement tool to assess how well states have implemented the DUR program and the effect DUR has had on patient safety, provider prescribing habits and dollars saved. In addition to promoting patient safety and positive health outcomes, the DUR program serves as a cost savings strategy by avoiding problems such as adverse drug interactions, drug-disease interactions, therapeutic duplication and over-prescribing by providers.

State Medicaid Disease Management Programs Reduce Expenses

Disease management programs are an emerging strategy for states to improve care and are designed to reduce overall expenditures, including drug expenditures, through more appropriate medication use for Medicaid beneficiaries with chronic illnesses. Both North Carolina and Washington have instituted successful disease management programs. For instance, North Carolina's Pharmacy Management Initiative has lowered drug costs of participants by 22 percent through use of a preferred drug list and is expected to save $9 million in 2004 through its pharmacy program that reviews the drug regime of nursing home residents and recommends changes consistent with appropriate prescribing practices.

States' Additional Techniques to Control Costs

States use a number of additional techniques to control Medicaid prescription drug costs.

- Approximately 9 states have strict limits on the number of brand name prescriptions that can be filled.
- About 37 states employ refill and/or monthly or annual prescription limits.
- Virtually all states (50 with the exception of Tennessee but including DC) report using day supply limits ranging from about a 30 to 100 day supply.
- About 32 states have fail-first or step therapy programs in place. Fail-First policies require that the patient fail on at least one other medication as a prerequisite for authorization of a specific, often non-formulary, medication. Step Therapy is a prescription pattern based on the state of illness that involves using the drug believed to be the most cost-effective first, followed by more expensive therapies.

Approaches for Cost Containment in Medicaid and the Private Sector Differ

The private sector utilizes a number of techniques to control their prescription drug costs, including significant consumer cost sharing, which would not be appropriate in the Medicaid setting. For example, private health plans use tiered copayments, which vary depending on whether the drug is generic, preferred, brand-name, or not included on a plan's formulary. Utilizing a range of copayments encourages patients to select lower-cost options. State Medicaid programs, however, may institute only a nominal copayment or coinsurance for prescription drugs, as Federal regulation sets a mandated $3 limit or a 5 percent coinsurance limit. Furthermore, as mentioned above, by law states cannot require prescription drug copayments for pregnant women, children under age 18, and hospital or nursing home patients who are expected to contribute most of their income to institutional care.

Some private insurers also require their members to obtain their prescriptions solely through mail-order pharmacies to control costs. In Medicaid, there is freedom of choice of provider and any willing provider. While Medicaid programs could apply for a waiver to use mail-order pharmacies to dispense medications to those with chronic conditions, states do not have the authority to restrict people with Medicaid to mail-order pharmacies for all their prescriptions.

Private insurers use formularies with tiered cost sharing and exclusion of certain drugs as a cost saving strategy. However, Medicaid must cover all FDA-approved drugs for every manufacturer that has a national rebate agreement, with some exceptions. States may utilize a preferred drug list, which would exclude certain drugs, but Federal law requires these excluded

drugs be made available through prior authorization. In addition, private insurers may not cover particular drugs, such as oral contraceptives and antihistamines, topical nasal products, and cough/cold products. These drugs account for 4 percent of Medicaid spending on prescription drugs (See Chart 9).

Conclusion

Mr. Chairman, members, thank you again for the opportunity to testify. CMS will continue to assist all states in adopting safe, proven approaches to lowering drug costs while providing access to prescription drugs and quality care. In addition, CMS will fulfill its role as a partner through the Federal Upper Limit and Medicaid Drug Rebate programs to ensure the government is a prudent purchaser of prescription medications. Thank you again for hearing my testimony, and I am happy to answer any questions you might have.